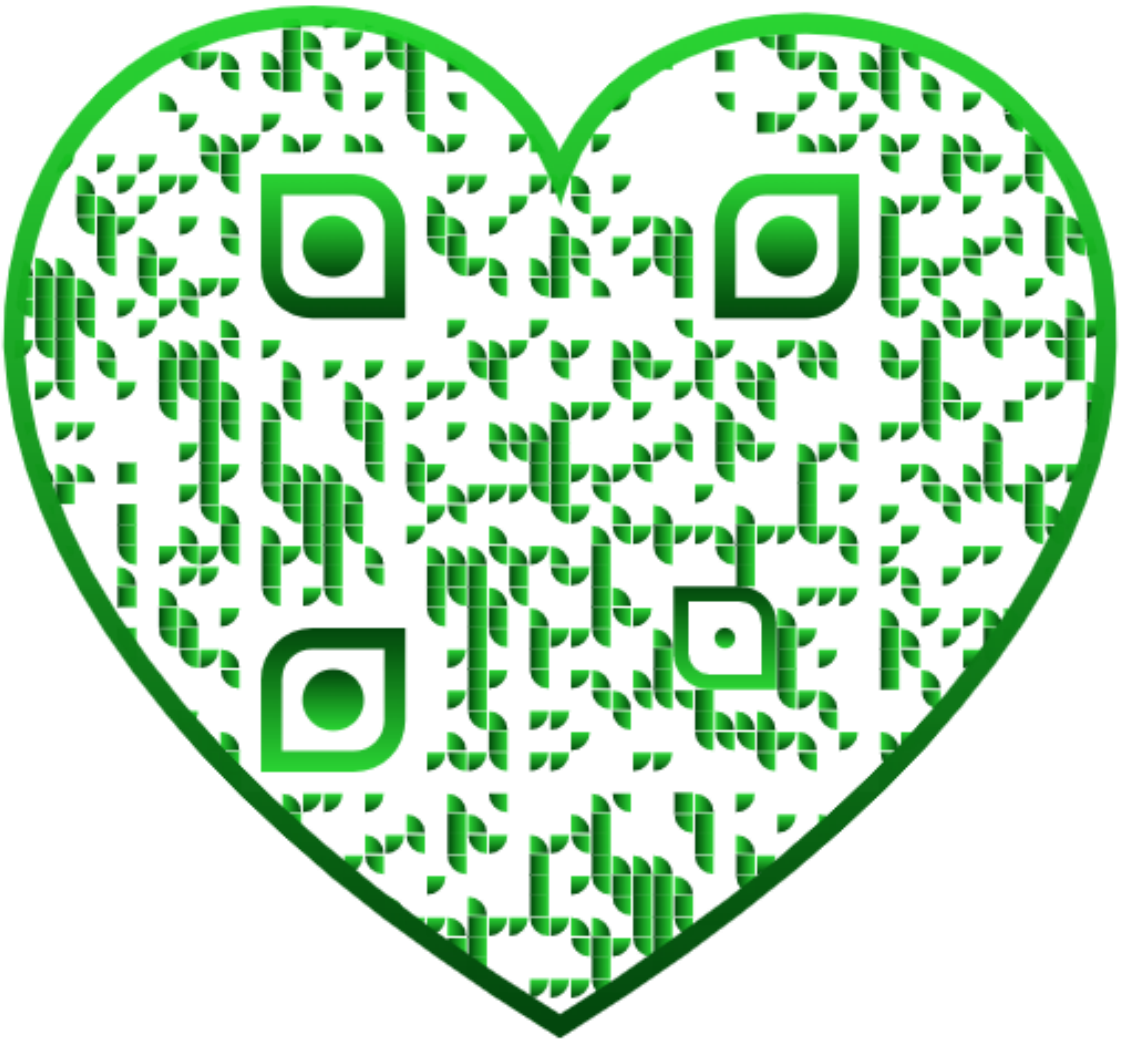
The table below is a running list of CDER's novel drugs approvals for 2024.

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date*
38.	Orlynvah	sulopenem etzadroxil, probenecid	10/25/2024	To treat uncomplicated urinary tract infections (uUTI)
37.	Vyloy	zolbetuximab-clzb	10/18/2024	To treat gastric or gastroesophageal junction adenocarcinoma
36.	Hympavzi	marstacimab-hncq	10/11/2024	To prevent or reduce bleeding episodes related to hemophilia A or B Press Release
35.	Itovebi	inavolisib	10/10/2024	To treat locally advanced or metastatic breast cancer
34.	Flyrcado	flurpiridaz F 18	9/27/2024	A radioactive diagnostic drug to evaluate for myocardial ischemia and infarction
33.	Cobenfy	xanomeline and trospium chloride	9/26/2024	To treat schizophrenia Press Release
32.	Aqneursa	levacetylleucine	9/24/2024	To treat Niemann-Pick disease type C Press Release
31.	Miplyffa	arimoclomol	9/20/2024	To treat Niemann-Pick disease type C Press Release
30.	Ebglyss	lebrikizumab-lbkz	9/13/2024	To treat moderate-to-severe atopic dermatitis
29.	Lazcluze	lazertinib	8/19/2024	To treat non-small cell lung cancer
28.	Niktimvo	axatilimab-csfr	8/14/2024	To treat chronic graft-versus-host disease (cGVHD)
27.	Livdelzi	seladelpar	8/14/2024	To treat primary biliary cholangitis (PBC)
26.	Nemluvio	nemolizumab-ilto	8/12/2024	To treat prurigo nodularis Drug Trials Snapshots
25.	Yorvipath	palopegteriparatide	8/9/2024	To treat hypoparathyroidism Drug Trials Snapshot
24.	Voranigo	vorasidenib	8/6/2024	To treat Grade 2 astrocytoma or oligodendroglioma
23.	Leqselvi	deuruxolitinib	7/25/2024	To treat severe alopecia areata
22.	Kisunla	donanemab-azbt	7/2/2024	To treat Alzheimer's disease Drug Trials Snapshot
21.	Ohtuvayre	ensifentrine	6/26/2024	To treat chronic obstructive pulmonary disease Drug Trials Snapshot
20.	Piasky	crovalimab-akkz	6/20/2024	To treat paroxysmal nocturnal hemoglobinuria Drug Trials Snapshot



19.	Sofdra	sofpironium	6/18/2024	To treat primary axillary hyperhidrosis Drug Trials Snapshot
18.	Iqirvo	elafibranor	6/10/2024	To treat primary biliary cholangitis in combination with ursodeoxycholic acid Drug Trials Snapshot
17.	Rytelo	imetelstat	6/6/2024	To treat low- to intermediate-1 risk myelodysplastic syndromes Drug Trials Snapshot
16.	Imdelltra	tarlatamab-dlle	5/16/2024	To treat extensive stage small cell lung cancer Drug Trials Snapshot
15.	Xolremdi	mavorixafor	4/26/2024	To treat WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) Drug Trials Snapshot
14.	Ojemda	tovorafenib	4/23/2024	To treat relapsed or refractory pediatric low-grade glioma Drug Trials Snapshot
13.	Anktiva	nogapendekin alfa inbakicept-pmln	4/22/2024	To treat bladder cancer Drug Trials Snapshot
12.	Lumisight	pegulicianine	4/17/2024	To use as an optical imaging agent for the detection of cancerous tissue
11.	Zevtera	ceftobiprole medocaril sodium	4/3/2024	To treat certain bloodstream infections, bacterial skin and associated tissue infections, and community-acquired bacterial pneumonia Press Release Drug Trials Snapshot
10.	Voydeya	danicopan	3/29/2024	To treat extravascular hemolysis with paroxysmal nocturnal hemoglobinuria Drug Trials Snapshot
9.	Vafseo	vadadustat	3/27/2024	To treat anemia due to chronic kidney disease
8.	Winrevair	sotatercept-csrk	3/26/2024	To treat pulmonary arterial hypertension Drug Trials Snapshot
7.	Duvyzat	givinostat	3/21/2024	To treat Duchenne muscular dystrophy in individuals aged 6 years and older Press Release Drug Trials Snapshot
6.	Tryvio	aprocitentan	3/19/2024	To treat hypertension Drug Trials Snapshot
5.	Rezdiffra	resmetirom	3/14/2024	To treat noncirrhotic non-alcoholic steatohepatitis with moderate to advanced liver scarring Press Release
4.	Tevimbra	tislelizumab-jsgr	3/13/2024	To treat unresectable or metastatic esophageal squamous cell carcinoma Drug Trials Snapshot
3.	Letybo	letibotulinumtoxinA-wlbg	2/29/2024	To temporarily improve the appearance of moderate-to-severe glabellar lines Drug Trials Snapshot
2.	Exblifep	cefepime, enmetazobactam	2/22/2024	To treat complicated urinary tract infections Drug Trials Snapshot
1.	Zelsuvmi	berdazimer	1/5/2024	To treat molluscum contagiosum Drug Trials Snapshot